

The Honorable Tommy Thompson
Secretary of Health and Human Services
440D Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

March 8, 2004

Dear Secretary Thompson:

In its advisory role under the Health Insurance Portability and Accountability Act (HIPAA), the Workgroup for Electronic Data Interchange (WEDI) periodically brings to your attention issues related to Administrative Simplification that it believes merit review and consideration by the Secretary.

This advisory follows on to our April 15, 2003, letter to you, where WEDI indicated its belief “that a substantial number of covered entities are not sufficiently far along to achieve compliance with HIPAA Transactions and Code Sets (TCS) standards by the October 16, 2003, deadline as required under the Administrative Simplification Compliance Act (ASCA).” It provides you with results of a public hearing that WEDI conducted in Tampa, FL on January 27, 2004, concerning progress by covered entities (healthcare providers, health plans, and clearinghouses) in achieving compliance with implementation of TCS standards.

In December 2003, WEDI invited covered entities to provide testimony relating to TCS standards implementation status, data content requirements, and implementation sequencing. WEDI received written and oral testimony from 51 entities, which was presented before a panel of healthcare industry representatives.¹

In general, hearing testimony indicated that:

- Covered entities are making good faith efforts in moving toward standard claim compliance under contingency guidelines issued by CMS in July 2003.
- HHS guidance to implement contingency plans has helped ease the transition.
- Currently, most covered entities are focusing on implementing compliant claims rather than on other TCS standards.
- Cost benefit from TCS has not been fully realized.
- A small number of large payers and providers account for a large but unknown volume of compliant transactions.
- A large but unknown number of covered entities have not yet achieved TCS standards compliance with their trading partners because of difficulties in completing testing with them.

¹ Names of entities providing testimony and hearing panelists are provided in Exhibit C to this letter. Written testimony is posted online at WEDI’s website, www.wedi.org.

- Payment disruptions to providers, providers dropping claims to paper instead of sending non-compliant electronic transactions, and health plans rejecting non-compliant claims have occurred during the transition.
- Covered entities are experiencing some data content challenges that require further guidance from the federal government.
- Covered entities need rapid deployment of standard provider and health plan identifiers in order to achieve interoperability

These findings are elaborated in Exhibit B: "Findings from Testimony."

WEDI believes that the industry will continue to progress toward TCS compliance. Because of the size and complexity of the healthcare industry, achieving compliance will take time. As a result, WEDI reiterates its recommendation from April 15, 2003, to allow the industry flexibility in achieving compliance with the TCS standards.

In response to the testimony, WEDI has considered the findings and is providing further recommendations to you to facilitate progress toward TCS compliance. Some of these recommendations require federal government action. Others can be undertaken by covered entities with encouragement from the federal government and collaborative organizations such as WEDI and its Strategic National Implementation Process (SNIP) initiative, which is playing an important role in developing implementation solutions.

These recommendations are elaborated in Exhibit A: "WEDI Recommendations."

We appreciate the effort made by the Department, in what most healthcare industry observers consider a large and complex task. We also appreciate the close working relationship WEDI has with CMS and the Office of HIPAA Standards. WEDI remains prepared to assist the Secretary with future implementation, and to respond to any questions that the Secretary may have on this matter.

Sincerely,

Ed Jones
Chairman

cc: Dr. John Lumpkin, Chair, NCVHS
Karen Trudel, Acting Director, HHS, CMS, Office of HIPAA Standards

EXHIBIT A

Outline of WEDI Recommendations

1. Continue HHS policy of allowing contingency plans
 - Focus on full compliance while maintaining contingency plans
 - Focus effort on implementation of non-claim transactions
 - Continue effort on outreach
2. Enhance implementation process
 - Do less at one time in a more realistic timeframe
 - Phase implementation by entity and by transaction
 - Establish standard communication protocols
 - Develop standard test data
 - Pilot standards prior to issuance of final rule
 - Establish authoritative technical interpretation of implementation guides
 - Educate system vendors on need for adherence to TCS regulations
3. Revise and enhance standards development process
 - Enhance outreach for provider input into standards development
 - Encourage business decision-makers to participate in standards development
 - Expedite process for correcting errors in standards
 - Develop solutions for addressing data issues with coordination of benefits
 - Address in a timely manner data content coding assessment and revision issues
 - Require the use of standard acknowledgement and error reporting
 - Conduct assessment of new technologies
 - Expedite implementation of unique identifiers
4. Validate costs and benefits of TCS implementation
 - Conduct realistic cost and benefit studies
 - Schedule review of such studies to ensure realization of net benefits
 - Identify further opportunities for achieving administrative simplification

WEDI Recommendations in Detail

1. Continue HHS policy of allowing contingency plans

- Focus on full compliance while maintaining contingency plans

Covered entities have implemented contingency plans as provided by the HHS guidance. This has prevented the “train wreck” that would have occurred if covered entities were unable to utilize any other form of EDI non-standard communication.

WEDI recommends a continuance of the contingency plans with an emphasis on moving health plans and clearinghouses into full compliance while providers complete testing and implementation. WEDI suggests that until a number of issues identified in testimony are resolved, covered entities may only be able to implement the standard format without supplying all of the required data content.

WEDI believes the movement towards the standard is inevitable, and that non-standard formats and content currently in use will not be cost justifiable over time. It would therefore be prudent to allow recipients of a transaction (e.g., health plans for 837, providers for 835) to determine if the transaction is usable, rather than modify the standard or enforce absolute adherence at this time.

This does not imply that the standard is inadequate or needs immediate modification. WEDI endorses the current standard until such time as it is officially modified.

WEDI believes that the complaint process for enforcement is a better means to resolve compliance issues than the operational rejection of patients’ healthcare benefits, as long as non-compliant transactions can be processed successfully.

- Focus effort on implementation of non-claim transactions

The industry has been very focused on the implementation of claims. **WEDI recommends that a renewed effort be initiated to identify and promote the net benefits of enrollment (834), premium payment (820), eligibility inquiry and response (270 and 271), remittance (835), authorization and referrals (278), and the claim status inquiry and response (276/277).** WEDI may initiate a Policy Advisory Group to determine effective measures to accelerate the use of these transactions.

- Continue effort on outreach

WEDI supports the need to continue efforts to assist those entities that may need assistance to resolve implementation issues. **WEDI recommends that the WEDI SNIP forum and Regional SNIP Affiliates be utilized to facilitate this effort, in addition to CMS continuing its Roundtables.**

2. Enhance implementation process

- **Do less at one time in a more realistic timeframe**

There was consensus that the TCS implementation attempted to accomplish too much at one time.

For example, the current TCS rule mandated several transactions at one time, even though each transaction represented a significant amount of effort. Claims status, eligibility, and authorization/referral can be separated from the claim and payment transactions and implemented on unique timelines.

The TCS implementation required analysis of the rule, vendor updates to software packages, vendor selection and other business decisions by the covered entity, and installation of vendor software updates at each selected site before testing could begin with trading partners. In many instances, this process consumed more than the full two years between effective and compliance dates *plus* the extension before trading partner migration could begin. Because of cash flow concerns, the healthcare industry is focused on the revenue-generating claim and remittance transactions to the exclusion of other mandated transactions.

WEDI recommends that future rules consider and establish realistic timelines for completing *all* required actions for successful implementation. If it appears that an implementation cannot be accomplished in a reasonable period, WEDI recommends that the implementation be subdivided into component parts that can be completed separately.

- **Phase implementation by entity and by transaction**

Because submitters cannot send claims until the payer is ready, many testifiers recommended that payers be required to be ready first. Implementation time lines should be developed for each covered entity category. Clearinghouses need a separate transitional time line due to the sheer volume of trading partners they must convert.

WEDI believes the effect of this sequencing will be a more logical implementation with emphasis on health plans to have necessary systems tested prior to mass conversion of providers and clearinghouses. It is unlikely that all submitters could be able to convert in a single day, but it is likely that the conversion could take place faster if providers were confident that payers and clearinghouses were prepared.

WEDI supports the concept of a staged implementation and recommends that software vendors be considered in the staging, since most providers, payers and clearinghouses use translators and other purchased software and are unable to be ready without availability of compliant software.

- **Establish standard communication protocols**

Some testifiers suggested that using standard communication protocols would simplify the technical aspects of migration. WEDI recognizes that this matter might be of concern to some, but suggests that other items should take higher priority. **WEDI recommends a review of communication and transmission processes currently being used and definition of acceptable communication and transmission methods.**

- **Develop standard test data**

Testifiers indicated problems of finding test data that were valid, compliant, and approved by CMS. During the development of HIPAA compliant transaction systems, there is a need to process valid transaction test data to ensure that the programming and development processes result in compliant transactions. However, to test appropriately, qualified test data also must include negative testing situations to test the editing processes that are used to validate compliance. This level of testing doesn't provide for end-to-end testing without manipulating the data to meet an organization's specific business needs.

WEDI recommends a feasibility study to develop national test data. The test data should include both positive and negative test data for each transaction. The database should include the current 4010 A1 version and the next version, so that as systems are changed to support a new version, both the new and prior version can be tested.

- **Pilot standards prior to issuance of final rule**

Many testifiers stated that proposed standards should not be adopted without an adequate pilot of the standard. This pilot would serve two purposes. First, it would identify flaws in the standard that could be corrected before a final rule is issued. Second, the pilot could determine if the proposed standards actually accomplish intended goals. The pilot must be thorough and robust. A limited pilot with a well-controlled predictable environment would not serve to uncover critical deficiencies in the proposed standard. **WEDI supports the concept of using pilot implementations for future standards.**

- **Establish authoritative technical interpretation of implementation guides**

WEDI recommends that an authoritative industry forum be established to answer questions, and that WEDI and the Designated Standards Maintenance Organizations (DSMO's) should be part of the effort to develop "Frequently Asked Questions". In addition, a balanced technical panel of experts should review all companion guides for consistency and appropriate content, and a directory to provide assistance to providers and their vendors should be published that is similar to a high-level industry roadmap.

- **Educate systems vendors on need for adherence to TCS regulations**

The TCS regulation defines a business associate, and enables covered entities to require the business associates to comply with all applicable standard specifications. It also requires agents or subcontractors to comply. Based on the input WEDI received from covered entities, particularly providers, there is sufficient evidence that software and billing systems vendors may not consider themselves required to modify their systems to comply with the TCS regulations.

WEDI recommends continued outreach to covered entities to ensure that their systems vendors, and those serving as business associates understand their responsibilities under the TCS standards regulations.

3. Revise and enhance standards development process

- Enhance outreach for provider input into standards development

The process used by the American National Standards Institute (ANSI) X12 standards development organization requires ANSI membership and application of ANSI rules to create or modify a standard. Participation in X12 may not be balanced or consistent with the needs of the general provider community. **WEDI recommends that CMS, DSMO's, WEDI, and the Standard Development Organizations (SDO's), collectively generate provider outreach, examine this issue and develop recommendations to resolve this issue.**

- Encourage business decision-makers to participate in standards development

Technical representatives often dominate standards organizations. There is a need to incorporate business knowledge of decision-makers in the process to identify whether proposed changes will reflect the utility, flow, and capture of information as it is used in business operations. There must be consideration for variations in the standard to reflect different subsets of business entities. For example, the data applicable to a dental, vision, or lab environment may have significant differences from that applicable to a physician's practice. **WEDI recommends that CMS, DSMO's, WEDI and SDO's examine this situation and determine what if any changes to the standards process might be warranted.**

- Expedite process for correcting errors in standards

The standards development process is lengthy and HIPAA requires a rules change to adopt a new version of the standards. A process is needed to fast-track corrections to a standard. **WEDI recommends that CMS, WEDI and the DSMO's assess this matter and determine whether an expedient change process should be developed.**

- **Develop solutions for addressing data issues with coordination of benefits**

Several testifiers mentioned issues associated with coordination of benefits (COB). One testifier felt HIPAA had the potential to improve COB processing, but the issues need to be addressed before this could occur.

A. Issues with COB data from providers

Capture of data for COB claims submitted from the provider is a concern. Two major issues for providers exist.

1. The industry has not achieved the 'critical mass' of payers and providers communicating payments using the HIPAA 835. Until that is accomplished, the act of creating an electronic COB claim requires considerable manual effort on the part of a provider to convert the paper information into data that can be entered into a billing system and be sent in the proper 837 4010A1 format for COB claims.
2. There is a lack of a standard 'HIPAA claim format' for billing services to payers. For example, a large group health plan may require a provider to submit all services (including employed physician charges) on an institutional format claim. Then, for COB claims, Medicare requires the institutional services and professional services (as defined by CMS) to be separated and sent to different intermediaries and carriers. Legacy systems and formats allowed for a simpler process of reporting billed charges, payments and adjustments, and amount due. The HIPAA COB claim is much more demanding in data content and quality. The splitting of the payment for electronic COB purposes is a problem for the provider. (Note: This issue pertains only to providers who submit both Institutional and Professional formats, which excludes most physicians. WEDI SNIP has a subgroup that has been working to identify those areas where differences exist among the various payers and how providers are required to bill. The list of differences is extensive.)

B. Other technical COB issues can be summarized as follows:

- Some institutional submitters are only able to report other payer information at the claim level and not at the line level. This may be an issue for some payers due to the design of the provider payment system or the way the primary payer submits the 835 data to the provider.
- There also are concerns over the continued requirement by some payers to receive paper copies to supplement electronic claim information.
- Some payers continue to use non-standard (proprietary) adjustment reason codes contained on paper payments, thus making it impossible for a provider to migrate to an electronic format for electronic COB.

- Some COB transactions in Version 4010 are accomplished using payments still received in a prior version of the 835 transaction. Validation software often will fail the transaction, as the codes used in previous versions are no longer allowed in the 4010A1 version of the code set.
- CMS has identified an issue with COB when more than one payer is primary to the billed payer.
- COB is further complicated when multiple payments, payment retractions, repayments, are received by the provider from a payer due to cycle bills and interim payments or appeals. In addition, a payer may make payment in error, for example, applying a contractual agreement when none exists and subsequently determining the patient was not covered.

These situations need to be tested, validated, and instructions given to trading partners regarding how to properly document and report this information electronically to a secondary payer.

WEDI recommends that an industry work group be established to determine options for resolving these issues and to research the matter of COB data requirements.

C. Issues with Medicare crossover

Payers and clearinghouses are having difficulty obtaining test files from Medicare contractors. It was felt that CMS had not provided clear direction on how to handle crossover claims and this might be delaying creation of test files. In particular, data item requirements were cited as an issue. Also, there was concern over the requirement to use the National Council for Prescription Drug Programs (NCPDP) format for some crossover claims. The version adopted under HIPAA does not capture some data elements needed for COB processing.

WEDI recommends that CMS review crossover requirements and determine whether use of the NCPDP standard and the adopted version is still appropriate. WEDI also recommends that CMS provide clear instructions to Medicare contractors on how to populate crossover data items in a standard manner.

- Address in a timely manner data content coding assessment and revision issues

WEDI recommends that the IG maintenance committee evaluate and consider Claim Adjustment Reason Codes usage be expanded to include more specificity.

WEDI recommends that code set maintenance should be restructured to a version release schedule of only once a year, where appropriate.

WEDI recommends that maintenance committees should ensure a balanced representation of the industry.

WEDI recommends that CPT guidelines and instructions should be specified for implementing CPT codes. The use of codes and descriptors apart from the CPT national standard limits the functionality of CPT and its uniform application and contributes to improper coding interpretations which are counter to the purpose of having national standard code sets.

- Require use of standard acknowledgement and error reporting

The hearing validated concerns that have been raised regarding the need to have standard methods to:

1. Report errors in data and conflicts with the implementation guides for the transaction being received by the trading partner (both batch and individual transaction level reporting).
2. Require a standard acknowledgement of a transaction (industry wide acceptance and standard usage of 997 and TA1 transactions, for example).
3. Report to a provider, at the claim level, ALL accepted and rejected claims. This is needed by providers to ensure all claims transmitted are accounted for, to correct and retransmit claims that error, and to gather the "Payer Claim ID or DCN" for the accepted claims.
4. Adopt unsolicited claim status transactions to allow payers to report delay in claim processing in order to eliminate unnecessary telephone calls. This need will partially be covered once the department releases the attachments rule.

There is much frustration in the industry on the different methods of reporting. Some are using old reports, while others have changed to the 277 unsolicited, and some are only using the 997. Other methods are being considered within X12, but clearly this has become an issue of urgent

concern. Providers can't determine where errors are without extensive work, which is delaying time to correct errors and is having a tremendous impact on outstanding AR for the provider.

WEDI recommends that a standard method of reporting as indicated above be adopted as quickly as possible. In addition, attention should be given to projects underway where reporting functions and transactions are being addressed as 'demonstration' projects in order to obtain the benefit of their experience

While there is no standard defined in the X12N Implementation Guides for the right way to do this, it would be very helpful for the industry to agree on recommended best practices to help reduce the impact of this problem. WEDI SNIP is nearing completion of a White Paper that may give this issue much-needed guidance. **WEDI recommends that the WEDI SNIP paper be considered by CMS for guidance, and that X12 establish more guidance on this part of transaction processing for later adoption by CMS.**

- **Conduct assessment of new technologies**

WEDI recommends that continual evolution of technology be recognized in the rulemaking process. Rules should be evaluated to assure they do not inhibit the adoption of new technologies that could increase the efficiency of business information exchanges.

Several testifiers indicated that the current transactions standards seem aimed at batch-oriented processing. They felt that standards must consider the trend toward real-time processing and use of the web. In addition, with the accelerated rate of new technological advances, the standards and rulemaking process would most likely be unable to keep pace. The standards should represent a base that all covered entities can use to transact with each other. However, the standards should not be considered as a ceiling that prohibits or constrains other means of conducting a business function. Finally, organizations should be encouraged to experiment with transactions processing that uses new technologies that eventually could become industry standards.

- **Expedite implementation of unique identifiers**

WEDI recommends that implementation of the National Provider Identifier and the Health Plan Identifier be expedited to allow covered entities to become fully interoperable. The exchange of this information is essential to routing of transactions to the intended receiver, and the validation of the identity of the covered entity.

Lack of the identifiers impedes the ability of the covered entities to realize the full potential cost benefit of the standards transactions.

4. Validate costs and benefits of TCS implementation

- **Conduct realistic cost and benefit studies**

WEDI has supported the development of standard transactions and codes set since its original recommendations were published in 1993. Standards are an important part of the healthcare industry's effort to simplify the administration of healthcare. The primary objectives are to reduce administrative expense and make quality healthcare available to everyone.

The cost of implementing the HIPAA TCS has exceeded the industry's expectations. The complexity of the systems, business changes, and the trading partner migration process must be considered in developing cost estimates.

WEDI recommends that realistic cost and benefit studies be conducted to validate proposed savings and to encourage industry movement toward cost-effective solutions.

- **Schedule review of such studies to ensure realization of net benefits**

The TCS rules projected significant cost savings to be realized over several years subsequent to implementation. It is important to evaluate the effectiveness of the rules in order to improve future projections and to enhance the regulatory process by understanding what worked well and what didn't.

WEDI recommends that HHS schedule follow-up studies to determine the effectiveness of the implementation.

- **Identify further opportunities for achieving administrative simplification**

There is significant opportunity for reduction in operating expense and attainment of administrative simplification in the future. WEDI believes that covered entities that have not yet completed transition do so as soon as possible. WEDI also believes that the standards be expanded to cover use for all healthcare transactions, thereby eliminating the costly burden of paper-based exchanges. WEDI supports every effort to achieve these goals.

WEDI recommends that the health care industry continue to identify ongoing opportunities to drive cost from the systems, and simplify the administration of the healthcare system.

EXHIBIT B

Findings from Testimony

Introduction

Following presentation of testimony at its January 27, 2004 hearing in Tampa, FL, WEDI evaluated written and oral testimony provided by 51 entities. Findings from that evaluation are:

- Covered entities are making good faith efforts in moving toward standard claim compliance under contingency guidelines issued by CMS in July 2003.
- HHS guidance to implement contingency plans has helped ease the transition.
- Currently, most covered entities are focusing on implementing compliant claims rather than on other TCS standards.
- Cost benefit from TCS has not been fully realized.
- A small number of large payers and providers account for a large but unknown volume of compliant transactions.
- A large but unknown number of covered entities have not yet achieved TCS standards compliance with their trading partners because of difficulties in completing testing with them.
- Payment disruptions to providers, providers dropping claims to paper instead of sending non-compliant electronic transactions, and health plans rejecting non-compliant claims have occurred during the transition.
- Covered entities are experiencing some data content challenges that require further guidance from the federal government.
- Covered entities need rapid deployment of standard provider and health plan identifiers in order to achieve interoperability

These findings can be classified in five categories:

- Trading Partner Compliance
- Regulatory Issues
- Communication Issues
- Data Content Issues
- Cost and Benefit Issues.

Detailed findings are discussed by category in the pages that follow.

Trading Partner Compliance

- **Trading partner dependency critical path**

The most common complaint was that the covered entity was unable to implement the new standard because the trading partner was not ready. The dependency on the trading partners to modify systems, conduct testing, and correct deficiencies became a critical path to compliance. This is true in either direction.

- **Volume and complexity of multiple testing partners**

The need for trading partners to conduct multiple tests, with multiple trading partners, generated a work queue that resulted in priority being given to large volume trading partners. Thus, an entity may be compliant with one trading partner, and unable to test with others simply due to the sheer volume and complexity of the testing process.

- **Software vendors not prepared**

A number of testifiers observed that software vendors were not prepared to install HIPAA compliant versions on a timely basis. In addition they pointed out many of these vendors were themselves not defined covered entities, and were therefore not obligated to meet the October 16, 2003 deadline.

- **Addenda delayed testing**

Complicating the implementation were changes introduced by the Addenda version of the standard, encouraging entities to delay testing rather than begin testing until modifications were adopted.

- **Test data**

Testimony was provided that explained the complications brought on by the strict nature of the standard edits, and the inability of the trading partners to complete testing due to the failure of one party to supply all of the required test data. This was further complicated by the periodic changes made by trading partners to adapt fixes to the programs thereby negating the previous test data.

Testing the transactions did not ensure the production exchange between trading partners was successful.

- **Lack of coordination**

The coordination between the trading partners, or lack thereof, contributed significantly to failure in many cases. For example, we identified cases where both the provider and the payer were prepared to submit compliant transactions, but one of the middleman trading partners was not prepared.

- **Medicare cross-over**

Medicare contractors have not completed the transition to the new standard for Medicare crossover claims. Health Plans are required to maintain dual systems until this task is completed.

Regulatory Issues

There were a number of issues and concerns regarding the Transactions and Code Sets regulation as follows:

- **Complexity of the transition**

WEDI heard testimony expressing concern that the HIPAA Transactions and Code Sets regulation requirement to initiate all transactions for all covered entities on the same date were simply too complex by the sheer magnitude of the transition. Attempting to coordinate all of the communications among the trading partners for an event of this nature was simply not feasible.

- **Impact of addenda and ASCA**

Changes to the standard from 4010 to 4010A1 prior to the October 16, 2003 implementation apparently caused a number of covered entities to delay the development and testing of the standard until the final version was released. Several entities commented that providers and vendors were concentrating on the Medicare program applications due to the requirements set down by ASCA to require electronic transactions. This came at the expense of other covered entities that were placed in queue until this task was completed.

- **Interpretation of technical requirements**

A number of the entities testifying described their inability to get clarification of the requirements or technical questions regarding the implementation guides from a single authoritative source. Interpretation of the Implementation Guide, and inconsistent application of the companion guides, which are not referenced in the regulation, has generated unintended variations in how the standard is being applied. The need was expressed for common companion guides and crosswalks in order to allow interoperability between providers and payers.

Testifiers stated that “plugging-in” default data does not allow interoperability. There were concerns regarding guidance being needed on implementation guide notes; identifying what data elements should actually be required or situational; establishing a cap on data elements that are determined to be necessary; eliminating data elements that are not necessary for adjudication or are not beneficial for patient care; and for looking at the burdens for data collection and who it falls on; and to provide guidance on which implementation guide should be used for certain claim types.

- **Standards development process**

There were additional concerns regarding the standards development process, the lack of participation of providers, and a general concern that the content standards were not piloted in the real world prior to adoption. There was also concern expressed over the need for regulatory action in order to incorporate a correction or minor change to the standards.

- **System vendor compliance**

Testimony was provided concerning dependence on vendors who were not covered entities under the regulation. It was reported that system vendors had not made necessary modifications to systems, had made changes that did not result in standard transactions, or were including the modifications in upgrade at a higher cost.

Some comments were received that suggested this contributed to requirement by a number of covered entities to implement contingency plans.

- **Code set concerns**

There is general agreement that there is a lack of specificity with respect to the claim adjustment reason codes and the remark codes in the ANSI ASC X12N 835 remittance advice standard sufficient to define the detailed reasons for payment or denial. Assistance in developing crosswalks and expanding the reason and remark codes were mentioned several times. There were concerns expressed regarding lack of consistency in the code sets and the values in the guides. Testimony was provided regarding the updates for the medical and non-medical code sets varying from once a year to several times a year making it difficult for payers, providers and their vendors to keep informed of the changes.

Testimony was received that indicated standard implementation guidelines for code sets usage are essential for uniform national application of the code sets. There was additional information received suggesting that if standard guidelines for medical code sets were adopted, many attachments would be eliminated. WEDI heard that although the CPT code set was specified as a HIPAA medical code set, the CPT guidelines and instructions for applying the codes were not specified as a national standard for implementing CPT codes, which causes interpretation issues for providers and payers.

- **Trading partner agreements**

The need to revise trading partner agreements has contributed to the delayed implementation. In some cases trading partners would not begin technical testing and implementation of the standards until a revised agreement was in place.

- **Acknowledgement and error reporting**

It was brought to our attention that a key requirement to successfully performing electronic data interchange depends on the ability of the trading partners to acknowledge receipt of the transaction and generate error reports. The current regulations have not adopted a standard, and some entities have voluntarily adopted the existing ANSI standards.

- **Contingency plan impact**

WEDI received testimony expressing concern regarding the continuation of the guidance to extend contingency plans. Some of the constituents believe the lack of enforcement is adding delay to the implementation process, while others believe the contingency plan needs to be extended on a case-by-case basis. Some suggested the contingency plan might need to be considered on a transactions basis.

- **Complaint process**

Testimony was received indicating that covered entities were reluctant to submit a complaint to the Office of HIPAA Standards, because they were either non compliant in some aspect of the regulations, were working diligently with the trading partner to resolve the issue or may even be concerned with damaging the relationship with the trading partner. One comment was received that indicated the complaint process would not serve to resolve the technical issue, and application of the contingency plan policy made certain deficiencies allowable.

Communication Issues

- **Poor communication between covered entities**

Throughout the testimony WEDI received numerous comments from the presenters that the communication process was inadequate to support the implementation of the standards. This evidence is expressed in many forms, but it essentially depicts the inability of a provider to resolve issues with multiple payers via several, and in some cases unknown, entities who currently provide the connection to a payer or a group of payers.

It demonstrates there often is not a direct connection to a given payer, and where instructions or changes to instructions need to be exchanged between a payer and a provider there is no certainty the instructions will be received or complied with by the middle entities. These multiple connections inhibit the smooth flow of information.

- **Need for authoritative source of information**

There was a general concern of needing a single authoritative source for information, notwithstanding the CMS FAQ website. Suggestions were made to create a directory of contacts for covered entities, issues logs, and follow-ups on questions raised at CMS roundtable discussions. There are questions that have not been responded to, or not published for all entities to have access to the answer.

- **Instruction in the implementation guides**

There was a significant issue with the instructions in the ANSI Implementation Guide and the inconsistency of the companion guides assembled by the payers. WEDI and the Council for Affordable Quality Healthcare (CAQH) recognized this potential problem more than a year ago and provided web space to consolidate the information in a common form. Nevertheless a common format for the guides was not universally used and the information is disseminated from point to point as needed.

The interpretation of the rules, the standards, and the IG generated actions by some payers that were not consistent with the majority. For example, it became an open debate as to whether compliance required the rejection of an entire transmission of claims. Some payers insisted this was the correct interpretation or were forced to take this approach due to purchased software limitations, and balance/control concerns. This supports the request for a central technical authority to resolve these disputes. The question of what constitutes compliance has become more of a concern than the successful exchange of data.

- **Communication limitations as a barrier to complete testing and production**

Some of those testifying noted that some health plans provide testing and production information on their website, but do not provide access to support personnel to resolve problems. This has slowed down or stopped progress to implementation in those cases.

Data Content Issues

The issue of data content will inhibit the continued successful implementation of HIPAA Transactions and Codes Set until it is resolved.

- **Incomplete data content**

The transition to the new standard format is generally successful between trading partners, because, the technical transmission requirements are exacting, and require significant testing prior to production. All of the content required by the standard is not being supplied in the majority of instances for a number of reasons, however this has generally not impacted the payment of claims.

Generally, we would observe the providers have converted the existing data content supplied on either the CMS 1500, NSF 3.01, or UB92 form. The conversion requires a crosswalk to the new values. It results in a transaction that is in the proper format, but incomplete with respect to required data. The transaction may be rejected by front end editing programs. It may be accepted for processing, unless the receiving payers rejected the transaction during the claim adjudication process.

- **Difficulty in collecting data**

Providers are having difficulty in collecting some of the required data. In other cases they are utilizing existing formats, and not to supplying all of the required data. This is do, in part to regulations that allow a clearinghouse to convert non-standard transactions to the standard transactions before submission to health plans. However the intent of the regulation is clearly to have the non-standard transaction contain the required values.

Providers and clearinghouses are also struggling to resolve issues with creating the required data to supply "compliant" data. This has resulted in delayed testing, and reprogramming on the part of the payer to manipulate a less than complete transaction.

It has not prevented payments from continuing to flow. Either the payer has bypassed the edit, or has accepted non-standard transactions as a contingency plan until the matter can be resolved.

- **Necessity of data content**

The question was raised as to the necessity of the data elements, the ANSI process of developing standard data elements, and the participation of providers in the development process. The standards have modified in many ways the current custom and usage of data, and have created issues where none existed prior to the transition.

There are in reality, a small number of data elements that both payers and providers would agree are generally required to process a claim transaction, and others where either the situation or the majority of major payers requires the data to adjudicate the claim.

WEDI heard from a number of testifiers that certain data elements are simply not required or available. The implementation guide attempts to resolve the issue of data content by including an element as a required component even when only a minority of payers, and or claim situations may require the element.

- **Data standards maintenance organization process**

We received comments regarding the slow and some times non-responsive change process, and the need to improved the Designated Standards Maintenance Organization process, particularly the conflict of authority for defining required elements.

We received comments that criticized the authority of the health plans to require a situational data element defined in the standard without making it part of a trading partner agreement. There are also accusations that some payers are continuing to establish or interpret data requirements in the companion documents that are not consistent with the majority of the payer community.

- **Lack of unique identifiers**

WEDI received comments that indicated the lack of unique identifiers inhibited the benefit of standard formats and code sets. NCPDP commented the implementation was impeded by the lack of National Provider Identifiers, and the lack of Health Plan Identifiers.

Without the unique provider identifiers in place, providers will be forced to maintain proprietary identifiers for each health plan. This is important because it is essential to the routing and the financial accuracy of the transaction. As a result Covered Entities will be required to maintain a variety of non-standard identifiers, and will be unable to realize the full cost/benefit of administrative simplification.

Cost and Benefit Issues

There are several financial issues related to the implementation of HIPAA Transactions and Code Sets that must be taken into consideration.

- **Transaction not fully applied**

WEDI heard testimony from many of the entities, that the return on the investment would eventually be positive, but not until the non-claim transactions became fully integrated into the healthcare system. Neither providers nor payers were fully applying the use of these transactions, and it was apparent from the accounting report of each of the entities that more progress was needed in this area. Several testifiers doubted there would be a return on investment.

The obstacles for implementation of non-claim standard transactions are similar to the claims reasons stated above, except that unlike the claim transaction the need for real time access to information is acute. Web access to the information is available as well as proprietary direct data entry systems.

- **Expense of implementation exceeded expectations**

The expense to implement the standard transactions has significantly exceeded previous expectations. The re-engineering of legacy systems, requirements to program changes required by the 4010A1 version, and necessity to maintain dual systems to support contingency plans, and the excessive amount of testing has impacted the implementation cost. Vendors have passed on the cost of transition to HIPAA to covered entities.

In many cases where providers were unable to acquire compliant software, the primary cause was the vendors' inability to afford the cost of development. This has also forced vendors to either leave the business or merge with large organizations to gain efficiencies. While vendors are not covered entities their customers and business associates are often covered entities who expected the vendors to comply with the regulations. This has not always been accomplished successfully.

As a result, providers were either forced or reluctant to initiate the transition to the standard transactions. Some have temporarily converted to paper transactions where permissible.

Implementation of the Privacy regulations in the same year placed a financial burden on all covered entities. Security regulations are beginning to compete for scarce resources, further impeding the implementation progress for those who postponed the conversion to the later part of 2003.

EXHIBIT C

WEDI Implementation Planning Committee

Co-chair: David S. Miller

Co-chair: James Daley

WEDI Hearing Panel

Moderators

Steve Lazarus
David S. Miller
Jean Narcisi

Members

George Arges
Donald Bechtel
Gene Carruth
James Daley
Ed Jones
Ruth Kennedy
Steve Lazarus
Mark McLaughlin
David S. Miller
Stanley Nachimson
Jean Narcisi
Jim Schuping
Jim Whicker

**WEDI
HIPAA Implementation Hearing
January 27, 2004
List of Organizations Testifying**

Adventist Healthplan
AFEHCT
All Children's Health System
Allina Hospitals & Clinics
American Academy of Pediatrics
American Clinical Laboratory Association
American Hospital Association
American Medical Association
Anthem BC BS
ASC X12
AAHP-HIAA AVMedHealth Plan
BC BS Massachusetts
Blue Cross Blue Shield Association
Blue Cross Blue Shield of South Carolina
Capital HIXNY
CareMedic
Claredi
Coshocton County Memorial Hospital
Delta Dental Plans Association
Florida Medicaid
Foresight, Inc.
Frontline Group
Gustafson Associates
Hawaii HIPAA Readiness Collaborative (RSA)
Henry Ford Health System
Highmark BCBS
HIMSS/Phoenix Health
HIPAA Collaborative of Wisconsin (RSA)
HR-XML
Illinois Dept. Public Aid
Louisiana Medicaid

Mayo Foundation
McKesson
Medical Group Management Association
Missouri Medicaid
Misys Health Care Systems
NCHICA (RSA)
NCPDP
NEBO Systems, Inc.
New Jersey Medicaid
NextGen
Open Application Group, Inc.
PayerPath
RMW Associates
Siemens
SpecLin
Tampa General Hospital
UnitedHealthcare
Vanderbilt University
Wakely & Associates
Webify Solutions